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EXAMINER
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ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/510,401	ARNAUT ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,13-18 and 23-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,13-18 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 3/29/2010 is acknowledged.

Claims 1, 3-10, 13-18 and 23-32 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-9, 23-24, 26-27, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "and has substantially no effect on dough rheology". The specification as originally filed has no support for this phrase.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-9, 23-24, 26-27, and 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is indefinite for "and has substantially no effect on dough rheology". The term "substantially" is not defined by the claims. There is no guidance provided by the

specification to show what is meant by substantially. The phrase “no effect on dough rheology" is also indefinite. It is not clear what kind of effect the applicants are referring to.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-4,6, 8-10, 13-15, 17-18, 25, 27, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenberg et al. (DD 156,714 A; hereinafter R1) in view of Olesen et al. (US 6,110,508; hereinafter R2)

8. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

9. Although there is no explicit disclosure of preventing or retarding staling during the baking process of the bakery products, given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and the improver would intrinsically prevent or retard staling during the baking process of the bakery products.

10. Given that the weakening of gluten is disclosed it is clear that the protease is added to the dough prior to baking as presently claimed.

11. It is also noted that the addition of protease and other enzymes such as amylase in order to increase the shelf life of bread (retard staling) is an old and known process in the art.

12. Regarding the ratio of activities at 25C and the optimum temperature for protease activity, it is obvious that a thermostable enzyme with a high optimum temperature for activity will be much more active than the same enzyme at much lower temperature e.g. 25C. The ratio of activity at a much higher temperature (thermostable enzyme) to the activity of the same enzyme at lower temperature will be intrinsically high as presently claimed.

13. R1 is silent regarding addition of other enzymes and emulsifier to the dough.

14. R2 discloses the use of lipase together with other enzymes such as cellulase, hemicellulase, xylanase, glucose oxidase, peroxidase, amyloglucosidase, and alpha-amylase in bakery products including bread (Col. 5, lines 33-46). Bacterial alpha-amylase is known in the art and is a thermostable enzyme. It would be obvious to those of skill in the art to select a thermostable amylase such as a bacterial amylase to add to the dough formulations.

15. R2 discloses that examples of other enzymes are a cellulase, a hemicellulase, a pentosanase such as xylanase (useful for the partial hydrolysis of pentosans which increases the extensibility of the dough), a glucose oxidase (useful for strengthening the dough), e.g. a fungal glucose oxidase such as Novozym 358.RTM. (a A. niger glucose oxidase), a protease (useful for gluten weakening in particular when using hard wheat flour), e.g. Neutrase.RTM., a peroxidase

(useful for improving dough consistency), a peptidase, a maltogenase, and/or an amylase, such as an amyloglucosidase (e.g. AMG.RTM. (an A. niger amyloglucosidase) and an .alpha.-amylase (useful for providing sugars fermentable by yeast). The other enzymes are preferably of microbial origin and may be obtained by conventional techniques used in the art as mentioned above. (col. 5, lines 33-47).

16. R2 teaches using emulsifiers such as mono and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides (DATEM), sugar esters of fatty acids, lactic acid esters of monoglycerides, polyoxyethylene stearates, phospholipids and lecithin in their dough improver (Col. 6, lines 46-56). These emulsifiers are used to improve dough extensibility as well as the consistency and storage stability of the bread.

17. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a thermostable protease as taught by R1 and include the improving enzymes and emulsifiers taught by R2 to receive the benefits of the dough improving properties of such enzymes and emulsifiers to prevent or retard staling in baked goods. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

18. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1 in view of Terada et al. (US 5,124,261; hereinafter R3) and Chernoglazov et al. (RU 2,177,799; hereinafter R4).

19. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above. R1 is silent regarding protease of *Thermus aquaticus* and Keratinase of *Bacillus licheniformis.*

20. R3 discloses a process for the production of aqualysin I employing a genetic engineering procedure by cultivation of *Thermus aquaticus* (Col. 1, lines 34-52 and Col. 8, lines 31-51).

21. R3 is silent regarding a keratinase enzyme.

22. R4 discloses a new keratinase from *Bacillus licheniformis.* The keratinase can be used in the food industry (Abstract).

23. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by including the protease and keratinase taught by R3 and R4. One would do so to receive the benefits of a thermostable protease and keratinase at least at the early stages of baking where the temperature is high enough for the activation of these thermostable enzymes and yet not that high to denature such enzymes.. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

24. Claims 5, 23, 24, 26, and 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over R1 as applied above, further in view of Stetter (US 5,714,373; hereinafter R5).

25. R1 teaches of preparing a heat stable thermitase from *Thermoactinomyces vulgaris* and using it in baked products as described above.

1. R5 discloses the isolation and identification of a thermostable protease from *Thermococcus* which has an optimum temperature range between 60C and 90C (col.7, lines 38-41).

2. It would have been obvious to one of ordinary skill in the art to use proteases which have an optimum range of activity in the 60C-90C as disclosed by R5.

3. Claims 5 and 26 are obvious due to the fact that serine proteases have a serine residue at the active site which acts as a nucleophilic residue in proteolytic activities, being active at neutral or alkaline pH.

4. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the thermostable proteases from various sources as taught by R1, R3, R4 and use them optimally at 60-90C as taught by R5.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. They are not deemed persuasive for the following reasons.

1. Applicants argue that Klingenberg et al. (R1) does not teach that the serine protease has a temperature activity optimum higher than 60C wherein the ratio of activity at the optimum temperature to the activity at 25C is higher than 10.

a. R1 clearly utilizes thermitase, the protease from Thermmoactinomyces vulgaris. The optimum temperature for this enzyme was known as early as 1969. Please see Odibo, F.J.C. et al. 1988. MIRCN Journal. 4: 327-332. R1 also discloses the optimum temperature at 60-70C (please see R1 at page 2, line 11). This enzyme has an optimum

temperature for activity at 70C. Such a thermophilic enzyme does not show any detectable activity at 25C. Therefore, the ratio of activity at optimum temperature to the activity at 25C is inherently greater than 10 or 15. This limitation in claim 1 does not add anything new to the claim.

2. Applicants argue that the serine protease having the recited properties can prevent or retard staling while having substantially no effect on dough rheology, nor is there any teaching or suggestion of using the serine protease is a sufficient amount to achieve these results.

a. Inclusion of proteases in bread dough as an antistaling agent has been known in the art for many years. The following passage is from Gray, J. A. et al. 2003 (Bread staling, Molecular basis and control. Comprehensive Reviews in Food Science and Food Safety. 2: 1-21. At bottom of page 10 " Van Eijk and Hille (1996) concluded that while the addition of excess concentrations of proteolytic enzymes would certainly be detrimental to the bread loaf, adding optimal levels of proteases to breads might increase their shelf life."

Then it is clear that proteases at optimal concentrations are beneficial processing aids in increasing the shelf life of bread.

3. Applicants argue that they do not concede that the crude enzyme preparations discussed in Klingenberg necessarily disclose serine proteases having the properties recited in the claims.

a. Klingenberg (R1) utilizes thermitase, the thermophilic protease from thermoactinomyces vulgaris having an optimum temperature for activity at 60-70C. This

enzyme has been presently claimed. Therefore, the Applicants are utilizing the same enzyme as disclosed by Klingenberg.

4. Applicants argue that Klingenberg does not describe any partially or highly purified forms of thermitase.

a. The paragraph quoted by Applicants mentions crude preparation, partially purified form and in highly purified form as disclosed by Klingenberg.

Even if such a disclosure was not provided by Klingenberg, those of skill in the art know that enzymes are prepared (from biological sources) in crude form, they are then partially purified (at certain steps of purification) and in order to be studied or used for specific purposes, they are highly purified (high specific activity). The determination of the form of the enzyme for a specific application is within the skill of the art.

5. Applicants argue that it is unknown what the effects of adding the crude preparations described in Klingenberg to the dough would be. In particular it is not known whether such crude preparations could prevent or retard staling while having substantially no effect on dough rheology.

a. As mentioned earlier, the contribution of proteases to retardation or prevention of staling in bread was known before the invention was made. The problem to be solved with a crude preparation (the reference is in German, the Examiner is not aware of the enzyme by R1 being crude or other forms) was to determine the activity and the concentration of the enzyme to be used in preparing the dough which were both within the skill of the art. A skilled artisan knows that when the crude preparation is too dilute

for the desired effect, the preparation should be concentrated or partially purified or even highly purified by utilizing conventional techniques in the art.

It should be realized once the use of thermitase in baking was disclosed by Klingenberg, manipulations of enzyme forms, the concentration used, optimization of the levels for a desired effect would all be within the skill of the art.

6. Applicants argue that as recited in claim 1, the protease is added to the dough prior to baking in an amount effective to prevent or retard staling.

a. The purpose of the protease is breaking down a certain amount of gluten. Therefore, it is added to the dough. The Examiner is not aware of any other situation wherein the protease is added to the baked bread. Even if the protease be added to certain dry flour compositions, when that dry composition is mixed with water to make the dough, the included protease would be reacting with the gluten in the dough. Therefore, Applicants assertions that the protease is added to the dough does not have any weight on patentability.

7. Applicants argue that Klingenberg (R1) neither teaches nor suggests that the enzyme is added to the dough prior to baking, because the thermitase could be used in the process of preparing a baked product without being added to the dough to be baked.

a. The protease enzyme must be added to the dough prior to baking to get the benefit. Even if the enzyme be added to the dry flour composition, after mixing the flour with water, the end result would be the same. The addition of enzymes, for their desired

effects, to the dough prior to baking is well known in the art. These applications include the addition of proteases to the dough prior to baking.

8. Applicants argue that the Examiner has not provided support for his position that the use of the terminology "weakening" necessarily means that the thermitase was added to the dough prior to baking.

a. The disclosure by Klingenberg clearly states that gluten is weakened in the preparation of bakery products. This is clearly indicative of the incorporation of the protease in the dough prior to baking. The “weakening” effect of protease is the result of its reaction with gluten in the dough.

On the other hand, incorporation of protease and amylase into the dough prior to baking, to increase the shelf life of bread (retarding the staling) is an old and known process in the art as mentioned above.

3. Applicants argue that other gluten hydrolyzing enzymes such as papain and thermolysin are not able to retard staling when added to bakery products, without adverse effect on the dough.

a. As mentioned above, proteolytic enzymes should be cautiously used in baking because too much of them would be detrimental to the dough structure. However, mesophilic enzymes such as papain, when used indiscriminately, would show the effect at ambient temperature while the thermophilic enzymes would show the effect when the temperature of the environment , e.g. oven, is raised. Too much of both mesophilic and thermophilic enzymes would be detrimental, of course at two different temperatures. Therefore, at optimal levels, proteolytic enzymes can be used to retard staling.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,197,352. This patent discloses the anti-staling compositions for bread comprising amylase and protease.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781